

### **REMARKS**

The Office Action mailed October 15, 2009 (hereinafter, "Office Action") has been reviewed and the Examiner's comments considered. Claims 1-11, 14-24, and 27-32 are pending in this application. Claims 28-32 are withdrawn. Claims 23-24 are canceled without prejudice or disclaimer herein.

#### **Claim Rejections - 35 U.S.C. § 102**

Claim 27 stands rejected under 35 U.S.C. § 102(b) as being anticipated by WO 95/09585 to Caro (hereinafter, "Caro"). Applicants respectfully traverse this rejection.

Independent claim 27 recites, *inter alia*, "the tube having a first portion with a constant inner dimension along a first portion of the central axis and a second portion with a variable inner dimension along a second portion of the central axis."

The Office Action alleges that Caro discloses "a second portion having a variable inner dimension (as better illustrated in Figures 6-8)." (Office Action, p. 2.) However, Caro FIGS. 6-8 illustrate only perspective views from the *outside* of the prostheses shown and there is no disclosure in the Caro specification regarding a variable inner dimension of the illustrated prostheses. Further, the outside views do not appear to illustrate a variable dimension as claimed. In any event, it is axiomatic that an illustration from the outside of a prosthesis does not provide definitive information with respect to the inside dimensions thereof. Accordingly, Caro does not show or describe at least the feature of a variable inner dimension along a second portion of the central axis, and therefore Applicants respectfully request favorable reconsideration and withdrawal of the rejection of claim 27 under 35 U.S.C. § 102.

#### **Claim Rejections - 35 U.S.C. § 103**

Claims 1-11 and 14-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro. Applicants respectfully traverse this rejection.

Independent claim 1 recites, *inter alia*, “a first diameter that tapers to a smaller second diameter adjacent said end formation.”

Independent claim 18 recites, *inter alia*, “a first diameter portion extending along a majority of the length of the tube and a second diameter portion positioned adjacent the enlargement, the first diameter portion having a diameter greater than a diameter of the second diameter portion.”

Independent claim 21 recites, *inter alia*, “the tube comprising a first diameter portion extending along a majority of the length of the tube, a second diameter portion with a diameter less than a diameter of the first diameter portion positioned adjacent the first enlargement.”

The Office Action alleges, “[t]apering of the tubular portion 5 near the end formations 2a and/or 3a would have been obvious (if not inherent) in order to form an elbow or in order to provide a soft tissue transition from an expanded stented portion (page 6, lines 6-10) to the flanged tissue attachment portions.” (Office Action, p. 3.) The cited passage from Caro states the following:

In order to maintain the tubing open and prevent collapse or kinking it is possible to use a stent or other structural support of plastic, metal or other material internally, externally or integral to the wall of the tubing.

Applicants respectfully submit that, rather than suggesting to one skilled in the art that the tubular portion adjacent the enlargement should be tapered, as claimed, the Caro disclosure suggests that a taper or reduced diameter portion would be problematic. Specifically, because Caro suggests the use of additional structure to “maintain the tubing open and prevent collapse or kinking,” one skilled in the art would not seek to reduce the diameter of the tubing but, if anything, increase the diameter thereof. The Office Action suggests that tapering would be obvious in order to form an elbow or to provide a transition from an expanded stented portion. However, there is no disclosure in Caro *where* the stent or structural support should be placed or that an expansion of the prosthesis would even occur. Indeed, the idea set forth in Caro that the structural support be integral to the tubing wall does not indicate an expanded region. Therefore, it is pure conjecture without evidence

that there would be either: a) an expanded portion from which to taper, or b) an expanded portion at a location along the prosthesis at a point that would permit a taper adjacent the end formation. Further still, even if it could be shown that the support region was an expanded region, it does not follow that there would be an adjacent tapered region, as that region would then be more likely to collapse or kink as suggested in the Caro disclosure.

Accordingly, Applicants respectfully submit that a *prima facie* case of obviousness is not established and that independent claims 1, 18, and 21, and claims 2-11, 14-17, 19-20, and 22 depending therefrom, are patentable over Caro. Therefore, Applicants request favorable reconsideration and withdrawal of the rejections of claims 1-11 and 14-24 under 35 U.S.C. § 103.

### **Conclusion**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

It is noted that the remarks herein do not constitute, nor are they intended to be, an exhaustive enumeration of the distinctions between the cited references and the claimed invention. Rather, the distinctions identified and discussed herein are presented solely by way of example. Consistent with the foregoing, the discussion herein should not be construed to prejudice or foreclose future consideration by Applicants of additional or alternative distinctions between the claims of the present application and the references cited by the Examiner and/or the merits of additional or alternative arguments.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-2191, under Order No. 101675.0070P2 from which the undersigned is authorized to draw.

Dated: January 15, 2010

Respectfully submitted,

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